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VALVE HOLDER FOR TRICUSPID HEART VALVE

BACKGROUND OF THE INVENTION

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Field of the Invention

This invention relates to prosthetic heart valves and more particularly to a device for holding and positioning the heart valve during surgical implantation.

DESCRIPTION OF PRIOR ART

Natural heart valves taken from animals, particularly porcine heart valves, have been widely used for several years in the replacement of diseased valves in humans. The porcine valve suitably treated with gluteraldehyde or other fixative solution is mounted on a cloth covered stent or supporting framework prior to implantation. The stent is typically an open cylindrical device having a gently scalloped base curve and three axially extending commissure support struts adapted to support the margins of the valve cusps as illustrated in U.S 3,570,014. The stent is constructed of metal or plastic, covered with a cloth material, and provided with a circumferential sewing cushion extending outward from the base.

To facilitate handling of the valve during implantation, valve manufacturers have provided various valve holding devices which attach to the valve and allow the surgeon to more easily place the mounting sutures and position the valve in the original valve annulus. Once the valve and sutures are in position, the valve holder is detached from the valve and the surgical implantation procedure is completed.

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Valve holders of the prior art consist in general of a support member sutured to the sewing cushion of the valve and an elongated handle which attaches to the support member by screw threads or other suitable means. The valve holder is separated from the valve by cutting the attaching sutures and withdrawing the handle and support member from the operating area. The handle may optionally include an elbow or other means to permit the valve to be angled relative to the main axis of the handle.

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In mitral and tricuspid valve replacement, the prosthetic valve is inserted into position with the cusps directed away from the surgeon. In this position the cusps of the valve are subject to damage from snagging in the surrounding anatomical profile as the valve is moved into position and difficulty is sometimes encountered in inserting the valve into the original valve annulus. The mounting sutures are also susceptible to looping over the commissure posts as the valve is moved into position. Even with the aid of a valve holder, placing the valve in position is a sensitive and delicate procedure.

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It is accordingly an object of the present invention to provide a valve holder for natural tissue prosthetic heart valves. It is a further object of this invention to provide a holder for mitral and tricuspid valves which facilitates the positioning of the valve within the original valve annulus. It is a yet further object of the present invention to provide a valve holder which permits the commissure support struts of the valve stent to be drawn toward one another prior to placement of the valve, thereby reducing the diameter of the leading portion of the valve and the possibility of snagging the valve cusps and damaging the delicate valve tissue. These and other objects of the invention will be apparent from the ensuing description and claims.

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Summary

The valve holder of the present invention consists of a central support member having three spaced valve support  
5 legs extending radially therefrom. A foot at the distal end of each leg is provided with thread guiding and attaching means. The central support member is provided with thread collecting means.

10 The valve holder is positioned on the sewing cushion of the valve stent with the legs of the holder in registry with the commissure support struts. The foot of each support leg is secured to the sewing cushion by means of retention threads which are placed through the valve  
15 holder and valve stent as follows.

The free end of one thread which is preferably a size 4-0 braided polyester suture is secured to the thread collection means of the central support member and passed  
20 through the guide means in the foot of one valve support leg and on through the underlying sewing cushion of the stent. The thread proceeds through the fabric cover at the tip of the proximate commissure support strut, across the valve orifice area to the tip of an adjacent  
25 commissure support strut, through the fabric cover at the tip of said strut and thence through the sewing cushion and overlying foot of the corresponding adjacent valve support leg. The end of the suture is thereupon attached to the foot of that support leg. The procedure is  
30 repeated with two additional sutures which are attached respectively to the remaining two suture legs.

When all of the sutures have been placed as described above, the valve holder may be drawn tightly against the  
35 sewing cushion of the stent by activating the thread collecting means to take up any slack in the sutures.

Further activation of the thread collecting means will result in increased tension on the sutures with the tips of the commissure support struts being drawn inward to impart a tapered configuration to the valve. This taper  
5 permits the valve to be guided into the original valve annulus more easily and with minimum danger of snagging or damaging the delicate valve cusp tissue. The retention threads extending across the valve orifice area between commissure support struts also reduce the possibility of  
10 the mounting sutures looping over the struts.

Once the valve is positioned in the annulus of the patient and the surgeon is ready to remove the valve holder, each retention thread is cut at the point between the foot of  
15 the valve support leg and the central support area. As the threads are cut, the commissure support struts are released from the restraints imposed by the threads and return to their normal configuration. The valve holder and handle are then separated from the valve with the  
20 loose ends of each thread remaining attached to the valve holder and being withdrawn from the valve as the holder is removed.

#### DESCRIPTION OF DRAWINGS

25 Figure 1 is a view in perspective of the valve holder of the present invention attached to a mitral heart valve stent.

30 Figure 2 is a plan top view in partial section of the valve holder of Figure 1.

Figure 3 is a side elevation view in cross section through the valve holder of Figure 2 taken on line 3-3.

Figure 4 is a top plan view of the thread collecting means utilized in the valve holder of Figure 1.

5 Figure 5 is a side elevation view in cross section of the thread collecting means of Figure 4 taken through line 5-5.

10 Figure 6 is a partial side elevation view in cross section of the valve holder and stent of Figure 1 taken through one leg thereof.

15 Figure 7 is a schematic view in perspective of the suture configuration securing the valve holder to the valve stent as illustrated in Figure 1.

Figure 8 is an enlarged top plan view of an alternate foot configuration for a valve support leg.

#### DESCRIPTION OF PREFERRED EMBODIMENTS

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Referring now to Figure 1, there is illustrated valve holder 10 attached to the sewing cushion 11 of valve stent 12. For clarity of illustration, the porcine tissue valve ordinarily mounted within the confines of the stent has  
25 been omitted from the drawings. Handle 13 shown in part is attachable to the valve holder by means of screw threads 14.

30 Valve holder 10 consists of a central support member 15 and three valve support legs 16 (two visible in Figure 1) extending radially outward from the central support member. Each leg terminates in a foot 17 which includes thread guide and attachment means 25 in the form of a circular opening. Central support member 15 consists of a  
35 cylindrical structure having one open end facing stent 12

and terminating at the other end in coaxial hub 18 extending outward from annular flange 19. Positioned within the confines of the central support member is thread collecting disc 20 which includes stub axle 28 extending  
5 into hub 18 as illustrated in detail in Figures 4-6.

With further reference to Figure 1, threads 22 are secured at one end to the thread collecting disc housed within the confines of the central support member and pass outward  
10 through windows 21 in the wall of member 15. Each thread passes through a guide means 25 in foot 17 of each respective valve support leg and thence through the underlying sewing cushion of the valve stent. Each thread continues to the tip or apex of the proximate commissure  
15 support strut where it passes briefly through cloth cover 23 and thereafter across the valley between commissure support struts to the next adjacent strut. The thread passes through the cloth cover at the tip of the adjacent commissure support strut and thence through the sewing  
20 cushion and foot portion of the overlying valve support leg, whereupon it is secured to the foot of said leg at thread attaching means 25.

Thread guide and attaching means 25 in the foot of each  
25 valve support leg is more clearly illustrated in Figure 2 which is a top plan view of the valve holder of Figure 1. In the illustrated embodiment, openings 25 extend into outward facing channels 26 in the leg portion immediately adjacent the foot, and such channels are effective to  
30 guide the threads over the knee of the leg.

The inner wall of central support cylinder 15 preferably includes a ratchet surface as illustrated in Figure 2 which, in cooperation with a pawl on the thread collection  
35 means, permits rotation of the collection means in only

one direction. This construction is most clearly illustrated in Figures 2 and 3 where the ratchet surface is indicated at 24.

5 Referring now to Figures 4 and 5, thread collecting means 20 is illustrated in detail and consists of a base plate 27 having stub axle 28 extending from one side thereof. Base plate 27 is further provided with pawl 33 which in the assembled valve holder engages ratchet teeth 24 to  
10 restrict rotation of the thread collection device. Base plate 27 is further provided with drill holes 32 as means for attaching one end of threads 22.

Also illustrated in Figures 2 and 3 are circumferential  
15 cleats 27 extending from the inner wall of hub 18 which, in cooperation with a circumferential groove in the stub axle of the thread collecting disc, provide a snap fit to restrain the disc against axial displacement while permitting free rotation. The circumferential groove of  
20 axle 28 is indicated at 29 in Figure 5 which is a cross section through the center of the thread collecting device. Axle 28 is further provided with threaded drill hole 31 adapted to receive the screw threads of handle 13 as illustrated in Figure 1.

25 The assembled valve holder is illustrated in cross section in Figure 6 which further illustrates the path of threads 22 proceeding from the central support area through the thread guide means in the foot of each leg of the valve  
30 holder and thence through the sewing cushion and cloth covering at the tip of the commissure support struts. The two threads illustrated in Figure 6 are, as explained above, two of three individual threads used to attach the valve holder to the valve stent. The configuration of the  
35 three threads in the assembled device is illustrated schematically in Figure 7 where X indicates the end of the

thread tied to the foot of the valve support leg and indicates the end of the thread attached to the thread collection device.

- 5 The thread guide and attaching means in the foot of each valve support leg may be a simple drill hole as illustrated in Figure 2 or a channelled opening *or angled slot* as illustrated at 34 in Figure 8.
- 10 The retention thread configuration as described and illustrated above results in the tips of the stent commissure support struts being drawn together as the thread collection device is rotated to wind one end of
- 15 spread of the commissure support struts, placement of the valve in a confined area is facilitated and the possibility of damaging the delicate tissue of the valve mounted within the confines of the stent is reduced. To release the valve after it is positioned within the valve
- 20 annulus, each thread is cut at a convenient spot over the valve support leg. As the thread tension is released the commissure support struts return to their normal spread. The threads passing through the valve stent remain
- 25 ends are withdrawn from the stent as the holder is removed from the area.

The proceeding description and drawings are to a specific preferred embodiment of the present invention and are for

30 purposes of illustration and understanding and not limitation. The key element of the present invention resides in the combination of the valve holder and the attaching threads which permit the threads to be collected by the valve holder in order to draw the tips of the

35 commissure support struts toward each other and provide a tapered valve configuration.